

**510(k) Summary for the FemVue™ Saline-Air Device**

APR 28 2011

**Date of Summary:** March 25, 2011

**510(k) Submitter and Primary Contact:** Lisa Peacock  
Vice President, Regulatory Affairs  
Femasys Inc.  
5000 Research Court  
Suite 100  
Suwanee, GA 30024  
Tel: 770-500-3910  
Fax: 770-500-3980  
LPEACOCK@FEMASYS.COM

**Device Common Name:** Contrast media syringe (as an accessory to an intrauterine catheter)

**FDA Device Classification Name:** Cannula, Manipulator/Injector, Uterine

**Product Code:** LKF

**Classification Regulation:** Unclassified

**Device Class:** Unclassified, Pre-Amendment 510(k) Submission

**Panel:** Obstetrics/Gynecology

**Indication for Use:** The FemVue Saline-Air Device instills a consistent alternating pattern of saline and air as a continuous stream of contrast media into the uterus and fallopian tubes to be used in conjunction with an intrauterine catheter for performance of sono-hysterosalpingogram (Sono HSG).

**Device Description:** The FemVue™ Saline-Air Device is a dual-barrel contrast media syringe that can be connected to an intrauterine catheter to instill saline-air contrast media during sono-hysterosalpingogram (Sono HSG) procedures. Sono HSG consists of an ultrasound evaluation of the fallopian tubes with or without assessment of the uterine cavity.

**Predicate Device:** Ackrad H/S Elliptosphere Procedure Tray K020954

## 510(k) Summary for the FemVue™ Saline-Air Device

**Summary of Testing:** The FemVue was tested by the following non-clinical methods to demonstrate that the device is substantially equivalent to the predicate device in functionality, safety, and effectiveness:

- Fluid and air instillation function of syringe
- Catheter attachment
- Single-hand actuation
- Delivers continuous and consistent stream of an alternating pattern of saline and air



DEPARTMENT OF HEALTH & HUMAN SERVICES

---

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Mail Center - WO66-G609  
Silver Spring, MD 20993-0002

APR 28 2011

Ms. Lisa Peacock  
VP, Regulatory Affairs  
Femasys, Inc.  
5000 Research Court, Suite 100  
SUWANEE GA 30024

Re: K110288  
Trade/Device Name: FemVue™ Saline-Air Device  
Regulation Number: None  
Regulatory Class: Unclassified  
Product Code: LKF  
Dated: March 25, 2011  
Received: March 28, 2011

Dear Ms. Peacock:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

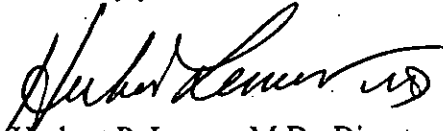
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Herbert P. Lerner, M.D., Director (Acting)  
Division of Reproductive, Gastro-Renal  
and Urological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Indications for Use**

510(k) Number (if known): K110288

Device Name: FemVue™ Saline-Air Device

Indications for Use:

The FemVue™ Saline-Air Device instills a consistent alternating pattern of saline and air as a continuous stream of contrast media into the uterus and fallopian tubes to be used in conjunction with an intrauterine catheter for performance of sono-hysterosalpingogram (Sono HSG).

Prescription Use   X    
(Part 21 CFR 801 Subpart D)


AND/OR

Over-The-Counter Use         
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER  
PAGE OF NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Reproductive, Gastro-Renal, and  
Urological Devices  
510(k) Number K110288